| In re Application of: | |) 5 T |
|-----------------------|---------------------------|---|
| Serial No: | Not yet Assigned Herewith |) Group Art Unit: 1619) Examiner: SHARAREH, S. |
| For: | HYDROMORPHONE THERAPY |)))) |

Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit herewith patents, publications and other information of which they are aware, which they believe an examiner may consider to be material to the patentability of the claims of this application, and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56.

While this Information Disclosure Statement may contain "material" information pursuant to 37 C.F.R. § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to herein is either "material" or "prior art" to the invention disclosed and claimed in the abovereferenced application unless specifically designated as such. Applicants specifically reserve the right, where appropriate, to avoid or antedate any such reference by the appropriate arguments or showings under 37 C.F.R. § 1.131 and § 1.608, or any other appropriate means.

A completed PTO Form 1449 listing each reference which is not a U.S. Patent application is submitted herewith, and it respectfully requested that an Examiner initialed copy of the PTO Form 1449 be returned to the undersigned.

| A copy of each reference therein listed accompanies this Information Disclosure Statemen | nt. |
|---|----------------|
| -OR- | |
| NO copies of the references therein listed accompany this Information Disclosure Statement | ent |
| under 37 C.F.R. § 1.98(d), as each was previously cited by or submitted to the Patent Office | in |
| prior application Serial No. 09/244,188, filed 02/04/1999, which this application relies upon | for an |
| earlier filing date under 35 U.S.C. § 120. | r † |

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This Information Disclosure Statement is not a representation that a search has been made or that no other information material to the patentability of this invention exists.

| | • |
|------|---|
| [x] | This Information Disclosure Statement is being filed within three months of the filing or entry of the national stage of this application, or before the mailing of a first Office Action on the merits, whichever is later. No fee is required under 37 C.F.R. § 1.97(b). However, in the event that more than 90 days from filing have elapsed and a first Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the fee required under 37 C.F.R. 1.17(p) to Deposit Account Number 01-1173. |
| | This Information Disclosure Statement is being submitted after three months from the date of filing or entry of the national stage or this application, or after the mailing of a first Office Action, whichever is later, but before the mailing date of either a final Office Action or a Notice of Allowance. |
| | □ The Commissioner is hereby authorized to charge the fee required under 37 C.F.R. § 1.17(p) to Deposit Account 01-1173 -OR- □ Certification as specified in 37 C.F.R. § 1.97(e) follows: |
| | Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application no more than three months prior to the filing of this statement. |
| | No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. |

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The Examiner is hereby requested to consider these references and other information and make them of record in the above-referenced application. Applicants respectfully submit that the claims of this application are patentable over the above-cited references and information. Examination and allowance of this application at an early date are requested.

Respectfully submitted,

Dhuey, Registration # 26.

Date: JULY 13, 2001

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on <u>July</u>, 12, 2001 ALZA CORPORATION

BY: Maria E. Valenzuela